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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,162	10/29/2003	Sujay Singh	IMG-00113.P.2.1	6582

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EXAMINER	
SAJJADI, FEREYDOUN GHOTB	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/696,162	SINGH, SUJAY	
	Examiner	Art Unit	
	Fereydoun G. Sajjadi	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to the preliminary amendment of 10/29/2003, canceling claims 50-113. No new claims were added and no claims were amended. Claims 1-49 are pending in the application.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. §121:

I. Claims 1-12, drawn to a transgenic vertebrate whose genome comprises a bacteriophage RNA polymerase transgene, classifiable in class 800 subclass 8.

II. Claims 13-29, drawn to a method of expressing a protein in a transgenic vertebrate whose genome comprises a bacteriophage RNA polymerase transgene, and a protein produced by said method, classifiable in class 800 subclass 4.

III. Claims 31-45, drawn to a method to produce an antibody against an antigen in a transgenic vertebrate whose genome comprises a bacteriophage RNA polymerase transgene, comprising introducing an immunogenic construct into said transgenic vertebrate, and an antibody produced by said method; classifiable in class 800, subclass 4, class 530 subclass 387.1.

IV. Claims 46, drawn to a method of producing a monoclonal antibody from the spleen cells of a transgenic vertebrate whose genome comprises a bacteriophage RNA polymerase transgene, classifiable in class 435, subclass 449.

V. Claims 48, drawn to a method of isolating antibody from the egg of a transgenic vertebrate whose genome comprises a bacteriophage RNA polymerase transgene, classifiable in class 530, subclass 412.

IV. Claims 47 and 49, drawn to a monoclonal antibody and a polyclonal antibody, classifiable in class 530 subclass 387.1.

Claim 30 link(s) inventions III, IV and V. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), 30. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

2. Should applicant elect any of Groups I, applicant is required to choose **one** specific organism, such as a bird, a fish, an amphibian or a mammal, as recited in claim 2-5. The bird, fish, amphibian and mammal are each structurally physiologically and functionally distinct and each capable of separate utility as transgenic animals. Therefore, the search and examination of said distinct organisms is not coextensive and would constitute undue burden. **This is not an election of species requirement.**

The inventions are distinct, each from the other because of the following reasons:

Restriction is deemed to be proper because these compositions and methods constitute patentably distinct inventions they are not disclosed as capable of use together or they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the inventions of Groups II-V are distinct, because Group II claims are directed to a method of expressing a protein in transgenic vertebrate whose genome comprises a bacteriophage RNA polymerase transgene. By contrast, the claims of invention III are directed to a method of producing an antibody against an antigen in a transgenic vertebrate whose genome an immunogenic construct. As such, the methods of Groups II and III are distinct, each from the other, as the immunogenic construct of Group III is not required for the method of Group II and the method of Group II may be used to express a protein that is not an antibody.

The invention of Group IV is directed to a method of producing a monoclonal antibody from the spleen cells of a transgenic vertebrate. As such, the method of Groups IV is distinct from the protein expression method of Group II and the antibody response to the antigen of Group III, and capable of separate utility. The invention of Group V is directed to a method of isolating antibody from the egg of a transgenic vertebrate. The invention of Group V is distinct from the methods of Groups II-IV, that do not require the egg of invention Group V. Each of the methods in Groups II-V are directed to separate goals and capable of separate use. Hence, Groups II-V are distinct, each from the other.

Inventions I and II-V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the transgenic vertebrate of Group I may be used to express an antisense transgene to control gene expression in said vertebrate, and not a transgene that encodes a protein, an antigen, or an antibody. Therefore the inventions of Groups I-V are distinct, each from the other.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper. The search of inventions in Groups I-V together would impose a serious search and examination burden, since the combined search of the different, transgenic animals, and methods or producing and purifying different proteins and antibodies, for prior art and the consideration of patentability of all claims is not coextensive and require different fields of search (see MPEP § 808.02).

3. This application contains claims directed to the following groups of patentably distinct species of the claimed invention:

Groups I-III – Applicant is required to choose a single species of bird, fish, amphibian or mammal, as recited in claims 6, 14-18 and 31-35. The bird, fish, amphibian, and the mammals consisting of primates, dogs, rats, sheep, etc. are each structurally and physiologically distinct and capable of separate use, requiring non-overlapping searches and examination, thus imposing a serious burden on the examiner.

Group II – Applicant is required to choose a single species of polymerase, as recited in claims 8, 20, and 37. The T7, SP6, and T3 RNA polymerases are each structurally distinct and capable of separate use, requiring non-overlapping searches and examination, thus imposing a serious burden on the examiner.

Group VI – Applicant is required to choose a single type of antibody, as recited in claims 47, and 49. The monoclonal and polyclonal antibody are each structurally distinct, produced and purified by separate methods and capable of separate use, requiring non-overlapping searches and examination, thus imposing a serious burden on the examiner.

Applicant is required under 35 U.S.C. §121 to elect a single disclosed species for each of the groups above, for prosecution on the merits to which the claims shall be restricted if no

generic claim is finally held to be allowable. Currently, claims 6, 8, 14-18, 20, 31-35, 37, 47, and 49 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, and/or because of the patentably distinct species are listed above, it would be unduly burdensome for the examiner to search and examine all of the subject matter being sought in the presently pending claims, and thus, restriction for examination purposes as indicated is proper.

Applicant is advised that the response for this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications regarding the formalities should be directed to Patent Analyst William Phillips, whose telephone number is **(571) 272-0548**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fereydoun G. Sajjadi whose telephone number is **(571) 272-3311**. The examiner can normally be reached Monday through Friday, between 7:00 am-4:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on **(571) 272-0731**. The fax phone number for the organization where this application or proceeding is assigned is **(571) 273-8300**. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

For all other customer support, please call the USPTO Call Center (UCC) at **(800) 786-9199**.

Fereydoun G. Sajjadi, Ph.D.
Examiner, USPTO, AU 1633

Q. JANICE LI, M.D.
PRIMARY EXAMINER